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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/227,881	01/11/99	NGUYEN T	07425.0057

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EXAMINER	
SHIBUYA,M	
ART UNIT	**PAPER NUMBER**
1635	13

DATE MAILED: 12/19/00

Pleas find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/227,881	Applicant(s) NGUYEN ET AL.
	Examiner Mark L. Shibuya	Group Art Unit 1635

☒ Responsive to communication(s) filed on *Oct 27, 2000*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1-126* is/are pending in the application.

Of the above, claim(s) *1-78 and 82-90* is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *79-81 and 91-126* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☒ The specification is objected to by the Examiner.

☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). *6 & 10*

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election with traverse of Group X (claims 79-81) in Paper No. 12, filed 10/27/00, is acknowledged. The traversal is on the ground(s) that examination of the entire application would not cause a serious search burden, and states that a simultaneous computerized search for nucleic acids of Groups II and the nucleic acids of Group III through VI could be run in a single such on databases available at the NIH. This is not found persuasive because searches of nucleotide sequences place heavy search burdens on the resources of the Office and because the different inventions of Groups II-VI are drawn to nucleotide sequences that are different and which the applicant has not asserted to be the same.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-78 and 82-90 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12, filed 10/27/00.

Claim Amendments

3. Acknowledgment is made of applicant's addition of new claims 91-126, filed 10/27/00.

Priority

4. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

The reference to the prior applications is not found in the first sentence of the specification, but in a later sentence.

Oath/Declaration

5. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

Non-initialed and/or non-dated alterations have been made to the oath or declaration in regard to the third inventor Pu Chen. See 37 CFR 1.52(c).

Furthermore, the page containing the signature of Pu Chen is numbered "-Page 3 of 4-". However, there already exists another Page 3 of 4 of the declaration that contains the signatures of Thai D. Nguyen and Jon R. Polansky. It is unclear as to whether the "-Page 3 of 4-" that contains Pu Chen's signature is to be included in the declaration filed 9/3/99, wherein the first and second pages of said declaration are numbered Page 1 of **4** and Page 2 of **4**. In other words, it is unclear as to whether this is a declaration totalling 5 pages, or 4 pages as explicitly stated. Because there are two Page 3s of 4, it is further unclear as to whether the third inventor, Pu Chen, attests to the statements within the declaration.

Information Disclosure Statement

6. The information disclosure statement filed 2/1/00, fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referring to Pine et al. (reference AL10, IDS filed 2/01/00), which incorrectly cites the publication date as "19990", has not been considered.

a. The following U.S. Application Serial Numbers are unavailable to the examiner, have not been considered, and will be considered as they do become available: 08/748,479, (applicant's reference AF3, IDS filed 2/01/00), and 08/822,999, (applicant's reference AG3, IDS filed 2/01/00). The citations to the U.S. Application Serial Numbers on the PTO-1449 have been removed as failing to comply with 37 CFR 1.98, because citations must have publication dates pursuant to 37 CFR 1.98, but U.S. Applications, (unlike U.S. Patents), do not have publication dates.

Specification

7. The specification is objected to because the specification at p. 53, lines 7-9, recites the terminology URLs. Embedded hyperlinks and/or other forms of browser-executable code are impermissible and must be deleted. The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01(p), paragraph I

regarding incorporation by reference. Furthermore if the application should issue and be placed on the Office web page, the URL may be interpreted as a valid HTML code and become a live web link, transferring the user to a commercial web site (in the instant case, Aerie Corporation, Birmingham, MI). Office policy does not permit the Office to link to any commercial site because the Office exercises no control over the organization, views or accuracy of the information contained on these outside sites.

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 79, 91, 92, 94, 97, 98, and 100 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34-37 of copending Application No. 08/938,669. Although the conflicting claims are not identical, they are not patentably distinct from each other because claims 34-37 of copending Application No. 08/938,669, drawn to nucleic acid molecules that comprise the sequence of SEQ ID NOs: 1 and 3, and recombinant DNA molecules that specifically hybridize to SEQ ID NO:1, would

encompass claims 79, 91, 92, 94, 97, 98, and 100 of the instant application, drawn to nucleic acids comprising SEQ ID NO: 1-3 or 34. (It is noted that both applications have the same inventive entity.)

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 U.S.C. § 101

10. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claims 79-81, and 91-126 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 79-81 and 91-126, drawn to "[a] nucleic acid", "[a] cell" and "[a] vector, read upon naturally occurring biological nucleic acids, which are products of nature that do not clearly show the "hand of man". Language at the beginning of this claim such as "An isolated nucleic acid", "An isolated cell", and "An isolated vector" would remove the instant rejection.

Claim Rejections - 35 U.S.C. § 112

12. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

13. Claims 79-81, 97-102, 109-114 and 121-126, are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for nucleotide sequences that are 1-3 or 34 and fragments of SEQ ID 1-3 or 34, and fragments of SEQ ID 1-3 or 34, wherein said fragments are regulatory regions, does not reasonably provide enablement for any fragment of SEQ ID 1-3 or 34 of any length that could be a functional regulatory region. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

a. The specification at pp. 13-25 contemplates numerous regulatory regions as small as six nucleotide in length.

b. The specification does not provide particular guidance or direction for fragments with biological function of any length. The term fragment would encompass a single nucleotide. The specification does not teach how to make and use fragments of SEQ ID 1-3 or 34 encompassing a nucleotide less than six nucleotides in length that would have biological function. Trial and error experimentation would be required of one of skill in the art to make and use any fragment of SEQ ID 1-3 or 34, such as a 1-mer or 2-mer or 3-mer, that could be biologically active as a functional regulatory region. Therefore undue experimentation would be required of one of skill in the art to make and use the claimed invention.

Claim Rejections - 35 U.S.C. § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 97-102, 109-114, and 121-126 are rejected under 35 U.S.C. 102(b) as being anticipated by Escribano et al., J. Biochem. 118 (5), 921-931 (1995) (applicant's reference AC, IDS filed 2/01/00).

a. Escribano et al., J. Biochem. 118 (5), 921-931 (1995), throughout the article and especially at p. 921, para 3-4, and p. 929, para 4, teach a fragment of SEQ ID 1-3 and 34 that is nucleotides 4862-5300 of SEQ ID 1-3 and 34, (as evidenced by Escribano et al., GenBank, Accession No.AB006686), phage vectors thereof and XL1-Blue cells thereof, and which further comprises a glucocorticoid response motif, a shear stress response motif and a NFκB motif, (as evidenced by applicant's admissions regarding the prior art in the instant specification at pp. 14 and 24).

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *Mark L. Shibuya (SRC),* whose telephone number is (703) 308-9355, and/or to the patent analyst, *Katrina Turner*, whose telephone number is (703) 305-3413.

16. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, *John LeGuyader* may be reached at (703) 308-0447.

17. Any inquiry of a general nature or relating to the status of this application should be directed to the *Group receptionist* whose telephone number is (703) 308-0196.

Mark L. Shibuya
Patent Examiner
Technical Center 1600
December 17, 2000

JOHN L. LeGUYADER
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